SECTION 6
510(k) SUMMARY

NOV - 9 2009

510(k) Notification K092735

GENERAL INFORMATION

Applicant:
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10700 Bren Road West
Minnetonka, MN 55343
U.S.A.
Phone: 952-930-6000
Fax: 952-930-6007

Contact Person:
Darlene Crockett-Billig
President
Experien Group, LLC
155-A Moffett Park Drive, Suite 210
Sunnyvale, Ca 94089
U.S.A.
Phone: 408-400-0856
Fax: 408-400-0865
Email: dcb@experiengroup.com

Date Prepared: September 18, 2009

Classification:
21 CFR§878.4810

Product Code:
GEX

Trade Name:
GreenLight™ XPS Laser System

Generic/Common Name:
Laser surgical instrument for use in general and plastic surgery and in dermatology

Predicate Device
GreenLight HPS™ Surgical Laser System & Accessories (K062719)

Indications For Use:
The GreenLight™ XPS Laser System is intended for the surgical incision/excision, vaporization, ablation, hemostasis and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue,

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muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. Suggested applications include:

General Surgery: Vaporizing, coagulating, incising, excising, debulking, and ablating of soft tissue as well as in endoscopic (e.g., laparoscopic) or open surgeries.

Gastroenterology: Tissue ablation and hemostasis in the gastrointestinal tract; esophageal neoplastic obstructions, including squamous cell carcinoma and adenocarcinoma; gastrointestinal hemostasis (including varices, espohagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, angiodysplasia, stomal ulcers, non-bleeding ulcers, gastric erosions); gastrointestinal tissue ablation (benign and malignant neoplasm, angiodysplasia, polyps, ulcer, colitis, hemorrhoids).

Gynecology: Vaporizing, incising, or coagulating tissue associated with treatments of conditions such as: endometriosis; cervical, vulvar, and vaginal intraepithelial neoplasia; condyloma acuminata; uterine septum; intrauterine adhesions; submucosal fibroids.

Head and Neck/Otorhinolaryngology (ENT): Tissue incision, excision, ablation, and vessel hemostasis.

Neurosurgery: Incising, excising, coagulating, and vaporizing neurological tumors of the firm textured type.

Ophthalmology: Post-vitrectomy endophotocoagulation of the retina.

Plastic Surgery: Vaporizing, coagulating, incising, excising, debulking, and ablating of soft tissue in endoscopic and open procedures.

Spinal Surgery: Percutaneous lumbar diskectomy.

Thoracic Surgery: Vaporizing, coagulating, incising, excising, debulking, and ablating of soft tissue, including lung tissue in thoroscopic or open procedures.

Urology: Cutting, coagulating, or vaporizing urologic soft tissues. Open endoscopic minimally invasive urological surgery (ablation, vaporization, incision, excision and coagulation of soft tissue) including treatment of: bladder, urethral & ureteral tumors; condylomas; lesions of external genitalia; urethral & penile; hemangioma; urethral strictures; bladder neck obstructions; and vaporization of prostate tissue for men suffering from benign prostate hyperplasia/hypoplasia (BPH).

Product Description

This GreenLight XPS Laser System consists of a console, a fiber optic delivery device, a camera filter and safety glasses that are required in order to use the system. The GreenLight XPS Laser System design and principles of operation are based upon the AMS GreenLight HPS Surgical Laser System & Accessories (K062719) that was successfully introduced to the market in 2006.

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Substantial Equivalence

The GreenLight XPS Laser System is substantially equivalent to the predicate device with regard to function, intended use, and physical characteristics. Any differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Thus, the proposed GreenLight XPS Laser System is substantially equivalent to the predicate device.

Testing in Support of Substantial Equivalence Determination

All necessary bench testing was conducted on the proposed GreenLight XPS Laser System to support a determination of substantial equivalence to the predicate device.

Summary

The GreenLight XPS Laser System is substantially equivalent to the predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

NOV - 9 2009

American Medical Systems, Inc.
% Experien Group, LLC
Ms. Darlene Crockett-Billig
President
155-A Moffett Park Drive, Suite 210
Sunnyvale, California 94089

Re: K092735
Trade/Device Name: GreenLight™ XPS Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: September 18, 2009
Received: September 21, 2009

Dear Ms. Crockett-Billig:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 5
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K092735

Device Name: GreenLight™ XPS Laser System

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Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K092735

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Urology: Cutting, coagulating, or vaporizing urologic soft tissues. Open endoscopic minimally invasive urological surgery (ablation, vaporization, incision, excision and coagulation of soft tissue) including treatment of: bladder, urethral & ureteral tumors; condylomas; lesions of external genitalia; urethral & penile; hemangioma; urethral strictures; bladder neck obstructions; and vaporization of prostate tissue for men suffering from benign prostate hyperplasia/hypoplasia (BPH).

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092735

Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use _____
(21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)